In re Application of:

FOSTER et al.

Application No.: 10/511,245

PATENT
Atty Docket No.: MAP1110

Filed: July 26, 2005

Page 2 of 12

## AMENDMENTS TO THE CLAIMS

Please amend claim 1 as indicated in the listing of claims.

Please add new claims 43 and 44

The listing of claims will replace all prior versions, and listings of claims in the application.

## Listing of the claims:

(Currently amended) A method for manipulating or formulating a solid substance which
melts under pressure of a gas without degrading at a temperature which is lower than the melting
point of the substance at atmospheric pressure comprising:

providing the substance in a pressure chamber having an inlet and an outlet, wherein the outlet is above the inlet:

applying to the substance a liquefied gas or dense gas to melt the substance without degrading the substance;

equilibrating the molten substance and the liquefied gas or dense gas to form a homogeneous solution; and

contacting the solution with a carrier fluid, wherein the carrier fluid is passed through the solution and is at substantially the same pressure as the liquefied gas or dense gas, to pass the solution from the pressure chamber through the outlet into a vessel of lower pressure than the pressure of the liquefied gas or dense gas and carrier fluid to form particles of the substance, and wherein further the solution is maintained below saturation.

- (Canceled)
- (Previously presented) The method of claim 1, wherein the carrier fluid is the same as the liquefied gas or dense gas.

In re Application of:

PATENT
Foster et al.

Atty Docket No.: MAP1110

Application No.: 10/511,245

Filed: July 26, 2005

Page 3 of 12

4. (Previously presented) The method of claim 1, further comprising allowing the substance

and the liquefied gas or dense gas to equilibrate for at least one minute before the contacting

step.

5. (Previously presented) The method of claim 4, wherein the equilibration step is for a

period of about 2 hours.

6. (Previously presented) The method of claim 1, wherein the substance is a pharmaceutical

or biological compound.

7. (Previously presented) The method of claim 6, wherein the substance is cyclosporine.

8. (Previously presented) The method of claim 1, wherein the temperature is between 5°C

and 150°C.

9. (Previously presented) The method of claim 1, wherein the pressure of the liquefied gas

or dense gas and carrier gas is between 5 bar and 200 bar.

10. (Previously presented) The method of claim 9, wherein the liquefied gas or dense gas is

carbon dioxide.

(Canceled)

12. (Previously presented) The method of claim 1, wherein at least 50% of the particles

formed are between 50 and 5000 nanometers in diameter.

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In re Application of:

Foster et al. Application No.: 10/511,245

Filed: July 26, 2005

Page 4 of 12

13. (Previously presented) The method of claim 1, wherein over 50% of the particles are less

PATENT

Atty Docket No.: MAP1110

than 5000 nanometers in diameter.

14. (Previously presented) The method of claim 1, wherein the particles are encapsulated

after the addition of an encapsulating material.

15. (Canceled)

16. (Previously presented) The method of claim 14, wherein the encapsulating material is

biodegradable.

17. (Previously presented) The method of claim 14, wherein the encapsulating material is

 $selected\ from\ the\ group\ consisting\ of\ polyethylene\ glycol,\ polyvinylpyrrolidone,\ poly(d,l-lactide-polyethylene)$ 

co-glycolide), poly cellulose acetate.

18. (Previously presented) The method of claim 14, wherein the encapsulated particles

contain a mixture or combination of the substance and a polymer.

Claims 19-38. (Canceled)

39. (Previously presented) The method of claim 6, wherein the substance is gemfibrozil or

fenofibrate.

Claims 40-41. (Canceled)

WEST\22075292.1 368008-000003 In re Application of: PATENT
Foster et al. Atty Docket No.: MAP1110

Application No.: 10/511,245 Filed: July 26, 2005

Page 5 of 12

42. (Previously presented) The method of claim 1, wherein the solution is passed by the carrier fluid from the pressure chamber through the outlet into a vessel of lower pressure via a pre-pressurized nozzle.

43. (New) A method for manipulating or formulating a solid substance which melts under pressure of a gas without degrading at a temperature which is lower than the melting point of the substance at atmospheric pressure comprising:

providing the substance in a pressure chamber having an inlet and an outlet, wherein the outlet is above the inlet;

applying to the substance a liquefied gas or dense gas to melt the substance without degrading the substance;

equilibrating the molten substance and the liquefied gas or dense gas to form a homogeneous solution: and

contacting the solution with a carrier fluid, wherein the carrier fluid is the same as the liquefied gas or dense gas and is passed through the solution and is at substantially the same pressure as the liquefied gas or dense gas, to pass the solution from the pressure chamber through the outlet into a vessel of lower pressure than the pressure of the liquefied gas or dense gas and carrier fluid to form particles of the substance, and wherein further the solution is maintained below saturation.

44. (New) A method for manipulating or formulating a solid substance which melts under pressure of a gas without degrading at a temperature which is lower than the melting point of the substance at atmospheric pressure comprising:

providing the substance in a pressure chamber having an inlet and an outlet, wherein the outlet is above the inlet:

applying to the substance a liquefied gas or dense gas to melt the substance without degrading the substance;

In re Application of: Foster et al. Application No.: 10/511,245 Filed: July 26, 2005

Page 6 of 12

Atty Docket No.: MAP1110

equilibrating the molten substance and the liquefied gas or dense gas to form a homogeneous solution; and

contacting the solution with a carrier fluid, wherein the carrier fluid is the same as the liquefied gas or dense gas and is passed through the solution and is at substantially the same pressure as the liquefied gas or dense gas, to pass the solution from the pressure chamber through the outlet into a vessel of lower pressure than the pressure of the liquefied gas or dense gas and carrier fluid to form particles of the substance, and wherein further the solution is maintained below saturation and the contacting is performed at constant temperature and pressure.